

REMARKS

This Amendment adds new claims 18 and 19, amends claim 1 and cancels claims 3 and 17. The features of new claim 18 are supported at page 6, line 33 to page 7, line 1, while the time range of claim 19 is set forth at page 6, lines 28-30. Claim 1 has been amended by incorporating the features of claim 3, by specifying that the bioactive component is either a bioactive glass or a bioactive xerogel, and by making clear that the claimed composite is a mixture of the bioactive component and the thermoplastic component, as taught at page 10, lines 25-29 of the specification. A version with markings to show changes made is attached as an Appendix. Claims 1, 2, 4-16, 18 and 19 are pending.

The 35 U.S.C. § 101 rejection of claim 17 has been mooted by the cancelation of that claim.

The 35 U.S.C. § 103(a) rejection of claims 1-17 over any one of U.S. Patent No. 5,552,454 to Kretschmann et al., U.S. Patent No. 5,964,807 to Gan et al. and U.S. Patent No. 6,027,742 to Lee et al. is respectfully traversed. The claimed composite is a mixture of a thermoplastic component and a bioactive component, which may be either a bioactive glass or a bioactive xerogel. The thermoplastic component is substantially made up of hydroxy acids or structural units derived from hydroxy acid derivatives, and has a molar mass within the range 10,000 - 1,000,000 g/mol.

The inventors have discovered that the claimed composite will remain moldable for a certain period of time after its temperature falls to a temperature considerably lower than the setting temperature (plasticization temperature) of its thermoplastic component if the thermoplastic component has a relatively high molecular mass of from 10,000 to 1,000,000 g/mol (Specification, page 6, line 28 to page 7, line 6).

Kretschmann et al. fails to raise a prima facie case of obviousness against the claimed composite. Kretschmann et al. discloses at least partly resorbable materials which contain selected oligomers and/or polymers of lower carboxylic acids whose molecular weight can range from 200 to 10,000 g/mol (Col. 4, lines 15-20). Although Kretschmann et al. discloses an upper limit of 10,000 g/mol, this reference fails to recognize the beneficial properties of a relatively high molecular weight thermoplastic component with respect to manipulating the composite once it has been placed in the body and its temperature is reduced below its setting temperature. Moreover, one of ordinary skill in the art is led to the use of lower molecular weight polymers by the express teaching of a preferred, lower range of from about 300 to about 5,000 g/mol.

Kretschmann et al. also fails to disclose, teach or suggest the bioactive glass or a bioactive xerogel features of the claimed

composite. Instead, Kretschmann et al. teaches the use of hydroxyl apatite and/or tricalcium phosphate as a bioactive component (Col. 5, lines 52-54). One of ordinary skill in the art is given no suggestion or motivation to substitute a bioactive glass or bioactive xerogel for the hydroxyl apatite and/or tricalcium phosphate expressly taught by Kretschmann et al. to be preferred.

Gan et al. also fails to raise a prima facie case of obviousness against the claimed composite, which is a mixture of a bioactive component and a thermoplastic component. Instead, Gan et al. discloses an intervertebral disc comprising a polymer foam coated with a sol gel bioactive material. Gan et al. thus teaches a structurally different article of manufacture than the claimed composite. Indeed, coating requires different properties than mixing, since in coating, no compatibility problems occur.

As discussed above, another feature of the claimed composite is that the thermoplastic component is substantially made up of hydroxy acids or structural units derived from hydroxy acid derivatives, and has a molar mass within the range 10,000 - 1,000,000 g/mol. Gan et al. fails to disclose the molecular weight of its thermoplastic component. In this regard, however, the object of Gan et al. is to provide for a construction that is in its final form before insertion into the patient's body. On column 9, lines 28-29, it is said that the substrate should generally have

a rectangular shape and that a cylindrical pad shape may also be envisaged. It is thus desirable that the Gan et al. product takes and keeps its final shape quickly after molding (or other manufacturing process). In contrast, the claimed composite can be molded into its final shape after being, for example, injected into a patient's body. One of ordinary skill in the art, seeking to achieve the object of the present invention, would not be motivated to use the quickly hardening material of Gan et al.

Lee et al. also fails to disclose or suggest a composite which can be molded into its final shape even after even after its temperature has been lowered to a temperature which is considerably lower than the setting temperature of its thermoplastic material. Instead, Lee et al. discloses a composite material comprising poorly crystalline calcium phosphate and a supplementary material. Importantly, the products prepared from the composite material of Lee et al. are bioresorbable hardware (col. 9, lines 64-65). A person skilled in the art would thus want to use materials that take and keep their final shape quickly after manufacturing, as in Gan et al. One of ordinary skill in the art is given no incentive to try to make a material that remains moldable for a certain period of time even after its temperature has been lowered to a temperature considerably lower than the setting temperature of its thermoplastic material, as in the claimed composite. Moreover, Lee

et al. does not disclose the use of bioactive glass or bioactive xerogel in its composite.

In short, none of these references, taken alone or in combination, disclose or suggest the claimed composite. Reconsideration and withdrawal of the obviousness rejection of claims 1-17 over any one of Kretschmann et al., Gan et al. and Lee et al. are earnestly requested.

It is believed that the application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 1-17, and issuance of a Notice of Allowance directed to claims 1, 2, 4-16, 18 and 19, are earnestly requested. The Examiner is urged to telephone the undersigned should he believe any further action is required for allowance.

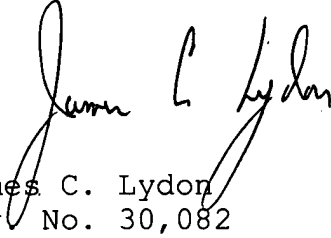
A Petition and fee for a two month Extension of Time are attached. It is not believed that any other fee is required for entry and consideration of this Amendment. Nevertheless, the

U.S. Patent Application S.N. 09/446,630
AMENDMENT

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Director is authorized to charge our Deposit Account No. 50-1258 in
the amount of any such required fee.

Respectfully submitted,



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Enclosures:
Appendix
Petition for Extension of Time